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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 5 : A61B 17/00, 17/12

A1

(11) International Publication Number: WO 92/22252

(43) International Publication Date: 23 December 1992 (23.12.92)

(21) International Application Number: PCT/EP92/01418

(22) International Filing Date: 18 June 1992 (18.06.92)

(30) Priority data:
9101051 18 June 1991 (18.06.91) NL

(71) Applicant *(for all designated States except US)*: ASHRIDGE AG [CH/CH]; Poststrasse 20a, CH-6300 Zug (CH).

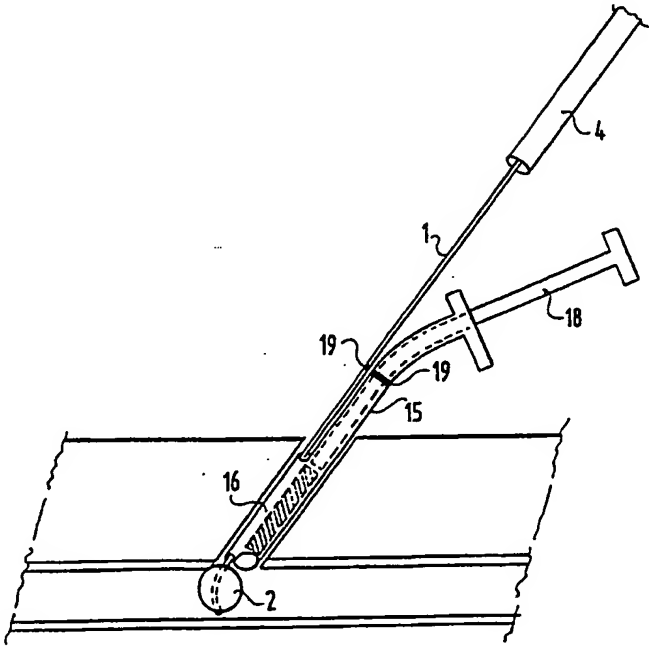
(72) Inventors; and
(75) Inventors/Applicants *(for US only)* : DEUSS, Jacobus, Antonius, Christiaan [NL/NL]; Heemskerklaan 5, NL-5694 CN Son En Breugel (NL). WITTENS, Cornelis, Hendrikus, Anna [NL/NL]; S. van Hagenstraat 55, NL-3062 XJ Rotterdam (NL).

(74) Agent: HOORWEG, Petrus, Nicolaas; Arnold & Siedsma, Sweelinckplein 1, NL-2517 GK The Hague (NL).

(81) Designated States: AT (European patent), BE (European patent), CH (European patent), DE (European patent), DK (European patent), ES (European patent), FR (European patent), GB (European patent), GR (European patent), IT (European patent), JP, LU (European patent), MC (European patent), NL (European patent), SE (European patent), US.

Published
With international search report.
Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.

(54) Title: SEALING DEVICE FOR A BLOOD VESSEL OR THE LIKE



(57) Abstract

A device for sealing with a plug a surgically arranged or other non-natural opening in a wall of a liquid-containing organ, such as a blood vessel, gall bladder and the like, in a living organism, wherein an elongate, hollow, flexible holder (15) is used, having on the distal end a spreadable element (2) and on the proximal end an operating member in communication with the spreadable element for carrying the element from a straightened position to a spread position and vice-versa in order to block the opening, to place the plug against the spreaded element and to remove the collapsed element alongside the plug sealing off the opening.

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SEALING DEVICE FOR A BLOOD VESSEL OR THE LIKE

The invention relates to a device for sealing with a plug a puncture, incision or surgically arranged or other non-natural opening in a wall of a liquid-containing organ, such as a blood vessel, gall bladder and the like, in a living organism.

It occurs frequently in surgery that an opening must be made in a blood vessel or other organ in for instance a human body either surgically or by means of a puncture via the skin, which opening must afterward be re-closed. This causes particular problems in the case of blood vessels such as arteries because a digital pressure has to be applied to the opening over a long period before sufficient tissue is formed to close the hole in natural manner by clotting of the blood. Since use is often made of blood diluting means this clotting process is poor and bleeding is a regular occurrence. It is sometimes even necessary to perform surgery. This results in a prolonged aftercare which is out of all proportion to the actual operation such as dottering or the like.

It is known to seal the blood vessel and the above-lying tissue by means of a plug of hemostatic and swellable material. The problem that occurs here is the precise placing of the plug in relation to the wall of the liquid vessel. It is namely inadmissible in the case of blood vessels for the plug material to enter the blood vessel, which can lead to blockages. If, however, the plug remains too far from the wall of the blood vessel after placing, blood loss will inevitably occur.

The invention has for its object to provide an auxiliary device with which placing of the plug can take place in precise manner so that the opening can be closed effectively.

The device according to the invention is distinguished by an elongate, hollow, flexible holder on the free end of which a spreadable element is fixedly arranged and an operating member communicating with the spreadable element for

carrying the element from a straightened position to a spread position and vice-versa.

With the elongate holder and the spreadable element on the end thereof it is possible, making use of the flexibility of the holder, to place the free end with the spreadable element through the opening into the organ. After spreading the element by means of the operating member the holder can be retracted again, wherein the spread element remains hooked behind the opening against the inner wall of the organ, that is, the blood vessel. The surgeon can then arrange a plug of suitable material along the flexible holder and push it through until it comes up against the spread element of the device. The spread element is subsequently reset into the straightened position and pulled out of the opening. The plug of swellable material expands and closes the opening in the wall of the blood vessel or organ, since the side of the plug facing the organ is arranged precisely in position.

According to a first embodiment the element is fixed to the elongate hollow holder in the form of an inflatable balloon, wherein the operating member is a pump communicating with the balloon via the hollow holder. In this embodiment spreading of the element is effected by pumping up the balloon so that the outside of the balloon comes to lie against the inner wall of the organ after the holder has been pulled back. After placing of the plug the pressure can be released from the balloon and the balloon deflated so that it can be withdrawn easily along the plug out of the organ. Optionally a vacuum can be applied in the balloon in order to further simplify withdrawal.

According to another embodiment of the invention the element is embodied as a number of strips lying in alignment with the elongate holder, the one ends of which are fixed to the outer end of the holder and the other ends to a common coupling piece, which coupling piece is embodied with a pulling member which is guided through the hollow holder.

The strips have a determined flexibility and stiffness so that in a released position they will extend in the line of the holder. In this situation the element strips and the holder can be inserted through the wall of the organ, whereafter a pulling force is applied to the pulling member. This

causes the strips to bend and therefore to spread so that the holder can be retracted again, wherein the outer sides of the strips come to lie against the inner wall of the organ. The plug can thus be accurately positioned against the strips, that is, against the wall of the organ.

By terminating the tensile force on the pulling member the strips will straighten again, whereafter the holder can be withdrawn with the element.

In a further embodiment of the invention the device for sealing the puncture or incision is formed by two parts, the first part being still the holder for guiding the spreadable element, and a second holder for bringing the plug in position.

According to a further development said holders are combined to a triple lumen catheter, the first lumen being connected to the spreadable element, the other two lumens being used for bringing the plug in position, said plug here being a two component glue.

Above mentioned and other features of the device according to the invention will be further elucidated hereinbelow with reference to a figure description of two embodiments. In the drawing:

fig. 1 shows a longitudinal section of a blood vessel embedded in surrounding tissue, in which blood vessel a sheath is arranged for surgical purposes, wherein a device according to the invention is used in the form of a balloon,

fig. 2, 3, 4, 5 and 6 show successive stages of the placing of the device according to the invention and the final sealing of the opening,

fig. 7 and 8 show a section corresponding with fig. 1 and 2 of a blood vessel, wherein a holder embodied with strips is used as device for sealing the opening,

fig. 9, 10 and 11 show a third embodiment of the sealing device according to the invention provided with a second holder for the plug,

fig. 12 and 13 show a fourth embodiment, wherein the first and second holder are united to a triple lumen catheter.

The device as shown in fig. 1-6 consists of an elongate, flexible holder 1, on the free end of which is arranged

a spreadable element in the form of a balloon 2. Only the outer end of the holder is shown in the figures, wherein it is assumed that the flexible holder 1 extends further than shown and is sufficiently long to reach the organ in the living organism from the outside. The other end of the holder is connected to a pressure pump 3, for instance bellows for manual operation, which is in communication with the hollow space in the holder 1 and therefore with the inside of balloon 2.

Shown in fig. 1 is a so-called introducer sheath 4 which is introduced beforehand in the blood vessel V of tissue W for instance for guiding into the blood vessel surgical elements such as for example a dottering balloon. For this purpose a guide wire 5 can already have been trained through sheath 4 which can likewise be used for introducing the holder with balloon 2. This is not essential and the wire 5 may also be removed beforehand. The introduction of the balloon 2 with holder 1 through the sheath 4 is recommended due to the easy introduction thereof. When the holder 1 and balloon 2 have been introduced, the balloon 2 can be inflated by means of the pump 3, as shown in fig. 2. It is noted that the balloon here virtually closes the passage of the blood vessel V but with an appropriate dimensioning sufficient space can also be left for a normal blood flow.

The sheath 4 is then retracted in the direction of arrow P2 and, after holder 1 has likewise been pulled back in the direction of arrow P2, the balloon will come to lie with the outer wall against the inner wall of blood vessel V, see fig. 3 and 4. A plug P can subsequently be arranged in the tissue W adjacent or around the holder 1, which plug is of suitable material, for instance material that is swellable on absorption of moisture and provided with clotting agents.

The plug P is guided inward into the tissue W until the underside O thereof comes up against the outside of the inflated balloon 2. This results in an accurate position of the plug P relative to the wall portion of blood vessel V so that no plug material P enters the blood vessel V.

By releasing the pressure out of the balloon 2 the latter will again assume the straightened position as shown in fig. 5 and the holder with the balloon can be retracted

from the blood vessel V in the direction of the arrow P2. Finally, the plug P will fill up the opening caused by the holder 1 and the blood vessel V is thus completely closed.

Due to this procedure it is now possible to effectively close the opening in the blood vessel wall V without applying much pressure thereto. Blood loss is hereby prevented and eventual aftercare for bleeding can be avoided.

The figures 7 and 8 show a second embodiment of the device according to the invention. the holder 1 is provided here with a number of strips 7 which are connected at the top end 8 to the extremity of holder 1 and the bottom end 9 of which is coupled to a common coupling piece 10. The latter is connected to a pulling element 11 which is guided through the holder 1 and coupled outside the holder 1 to a pulling means, for instance an eye (not shown).

By pulling the pulling element 11 in the direction of arrow P3 the coupling piece 10 is moved toward the end 8, whereby the strips 7 will bend in bulbous manner and be spread away from each other. With a sufficient curvature as according to the dashed line 12 the outside of the strips 7 will come up against the inner wall of the blood vessel V, whereafter the plug material P can be arranged against the strips 7. In the same manner as described above the position P is thus accurately determined and, after release of the pulling element 11, the holder 1 with the element strips 7, which have assumed the position according to fig. 7, can be withdrawn from the organ and tissue. The plug will subsequently close up the opening caused by the holder 1 and assume the position in fig. 6.

In the figures 9, 10 and 11 a third embodiment of the sealing device according to the invention is disclosed. In said figures the same reference numerals are used for the same parts of the device.

In said third embodiment the device consists of two holders. The first holder 1 is a thin shaft balloon catheter, e.g. an embolectomy catheter with a shaftdiameter of max. 3 French and a length of approximately 40 cm. The plug holder 15 is a flexible hollow tubular device of which the distal part is loaded with a collageen plug of approximately 4 to 5 cm. The plug holder has a provision 16 to allow it to be

hooked on the free exposed part 1' of the embolectomy catheter 1 during the procedure in a monorail fashion and to advance it over the shaft of the balloncatheter. Said provision 16 on the plug holder 15 is a short tube with an internal diameter that accommodates the shaft 1 of the balloncatheter and has a slit 17 lengthwise. By pressing this part of the plug holder between thumb and indexfinger this small tube opens and the shaft of the balloncatheter can be inserted in this space. Releasing the fingers closes this space around the shaft of the balloncatheter whereupon the plug holder can ride in a monorail fashion over the shaft of the balloncatheter. Inside the plug holder 16 is a stamp 18 inserted which reaches the plug P and which can be used to deliver the plug in place by keeping the stamp fixated and simultaneously withdrawing the hollow plug holder.

Above device can be used as follows.

The introducersheath 4 of the clinical procedure is still in the bloodvessel. The balloncatheter (e.g. a 3 French embolectomycatheter) is advanced through the hemostatic valve of the introducersheath, and advanced untill it is out of the distal end and in the free bloodvessel. See fig. 1. Now the balloon is inflated and both the introducersheath and balloncatheter are withdrawn until the inflated balloon reaches the hole in the vesselwall and closes this hole off. The introducersheath 4 is withdrawn another 10 cm to expose outside the body approximately 10 cm of balloonshaft 1. For this reason the balloncathetershaft should be about 40 cm. This situation is shown in fig. 9. While the proximal part of the balloncatheter is kept under pulling pressure to make sure that the balloon is closing off the hole in the vessel, the flexible plug holder 15 is hooked on the shaft of the balloncatheter. This is shown in fig. 9 and fig. 10. The plug holder is now advanced over the shaft of the balloncatheter in a monorailfashion until markers 19 on the plug holder 15 and the shaft 1 of the balloncatheter corresponds. This means that the distal part of the plug holder has reached a position just above the bloodvessel.

This situation is shown in fig. 10. The balloon will now be deflated. While the stamp 18 is kept in position, the plugholder 15, together with the balloncatheter 1 is

withdrawn. This action releases the plug just above the bloodvessel. As the collageen plug is thrombogenic, it will provide for an immediate and effective closure of the hole in the bloodvessel.

In the embodiment according to fig. 12 and 13 the two holders 1 and 15 for the speadable elements and plug positioning holder are united.

Here both holders are formed as a triple lumen catheter, one lumen of which is prolonged at the distal end over approximately 15 mm, whereas the distal end is connected to the inflatable balloon 2.

The outer diameter of the triple lumen catheter 20 is such that it is possible to introduce the catheter into the introducersheat 4, which was already positioned during surgical actions.

The lumen connected to the balloon can be connected to a syringe 21 so when pressing the syringe the balloon can be inflated.

The two other lumens are proximal connected to a double syringe, a so-called two component syringe filled with a two component fibrin glue, for instance tissue collagen.

The catheter can be used as follows. As soon as the catheter is brought in the blood vessel the balloon can be inflated. After removing the introducersheat from the blood vessel far out of the body, the catheter with the inflated balloon can be withdrawn also until the balloon will close off the puncture in the blood vessel. The openings of the double lumen are now approximately 15 mm above the wall of the blood vessel.

The two component glue can now be injected by means of the double syringe into the space just above the wall of the blood vessel. Due to the activated hardening elements in the fibrin glue, said glue will be hardened out, and will form a solid plug for sealing off the blood vessel. Prior to the final hardening of the glue the balloon is deflated and removed.

The invention is not limited to the above described embodiments.

It will be apparent that with the device according to the invention no alien material remains behind in the organ or blood vessel so that no risk of blockage or damage in the organ will occur.

CLAIMS

1. Device for sealing with a plug a surgically arranged or other non-natural opening in a wall of a liquid-containing organ, such as a blood vessel, gall bladder and the like, in a living organism, **characterized by** an elongate, hollow, flexible holder, on the free end of which a spreadable element is fixedly arranged and an operating member connected to the spreadable element for carrying the element from a straightened position to a spread position and vice-versa.

2. Device as claimed in claim 1, **characterized in that** the element is arranged on the elongate hollow holder in the form of an inflatable balloon, wherein the operating member is a pump communicating with the balloon via the hollow holder.

3. Device as claimed in claim 2, **characterized in that** in the straightened position the diameter of the inflatable balloon is at least three times the outer diameter of the holder.

4. Device as claimed in claim 1, **characterized in that** the element is embodied in the form of at least two strips, wherein the one end of the strip is connected to the outer end of the holder and the other ends are mutually coupled, wherein the coupled ends are connected to a pulling member which is guided through the hollow holder.

5. Device as claimed in one of the previous claims, **characterized in that** a second holder is provided for introducing a plug just above the inflated or spreaded element.

6. Device as claimed in claim 5, **characterized in that** the second holder (15) is provided with a guide (16) cooperating with the first holder (1) of the spreadable element.

7. Device as claimed in claim 5, **characterized in that** both holders 1 and 15 respectively are united in a single holder provided with three lumen, one lumen of which is prolonged and connected to the spreadable element.

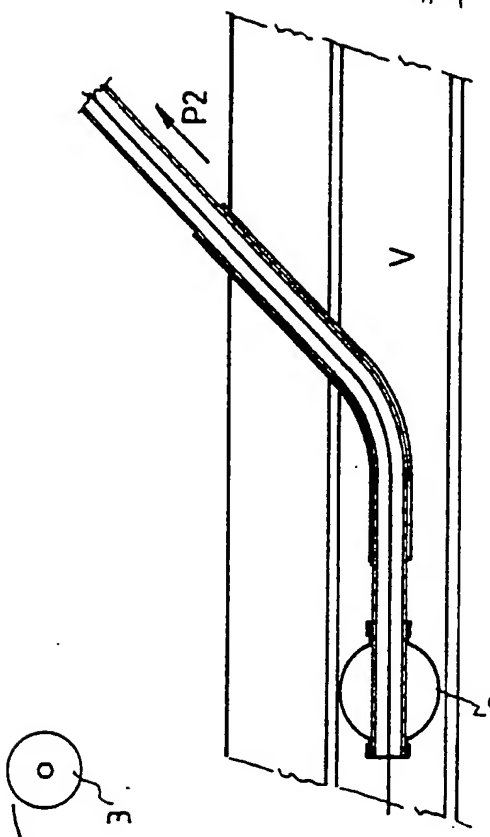

Fig 2

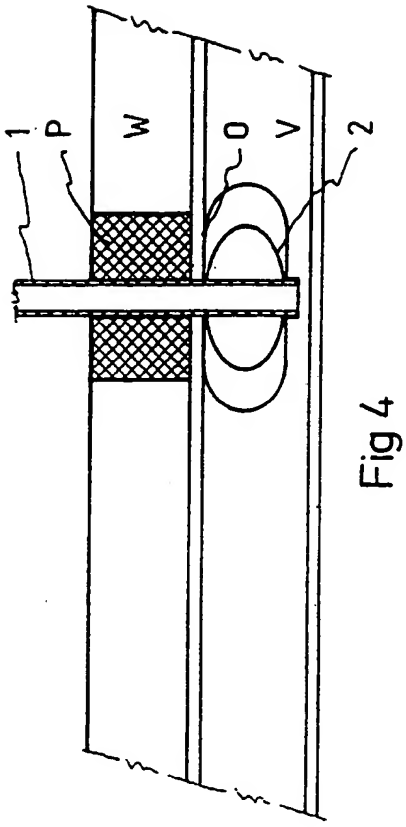

Fig 4

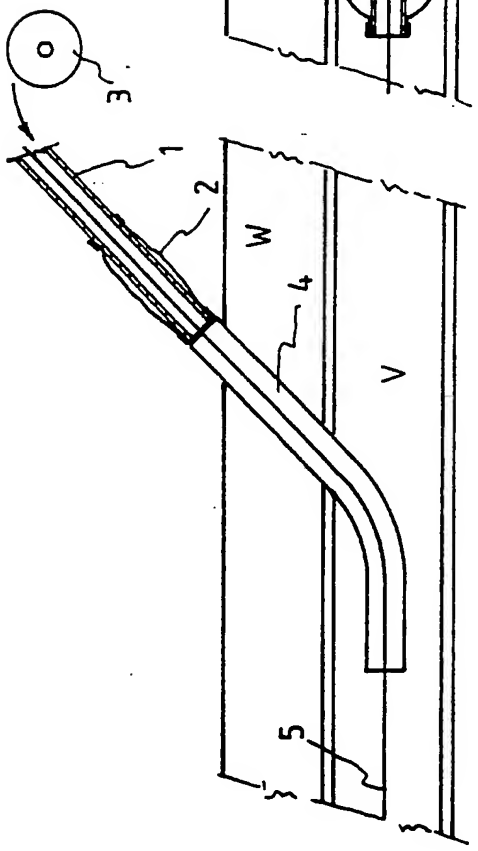

Fig 1

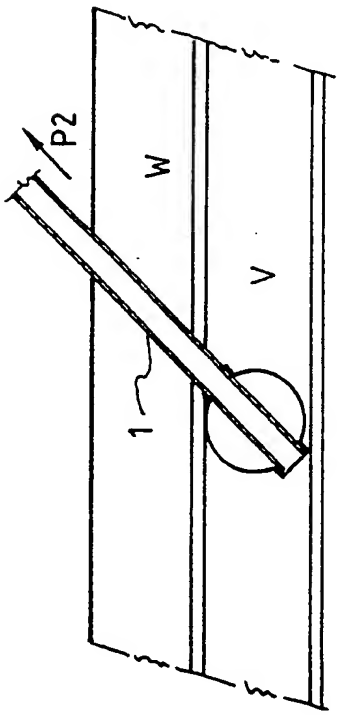

Fig 3

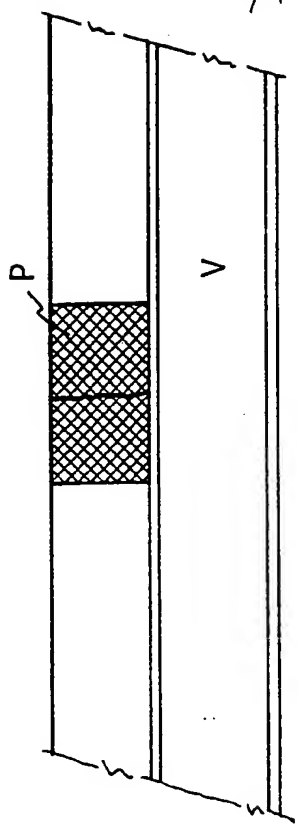

Fig 6

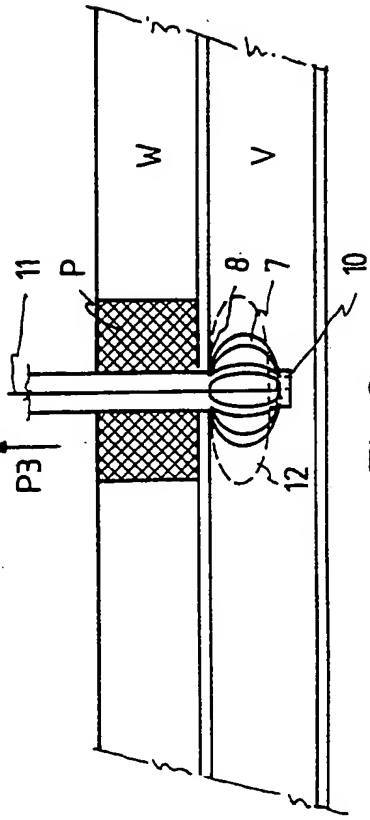

Fig 8

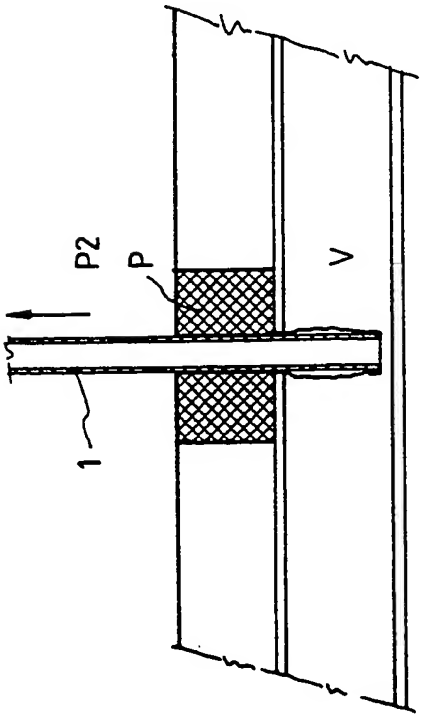

Fig 5

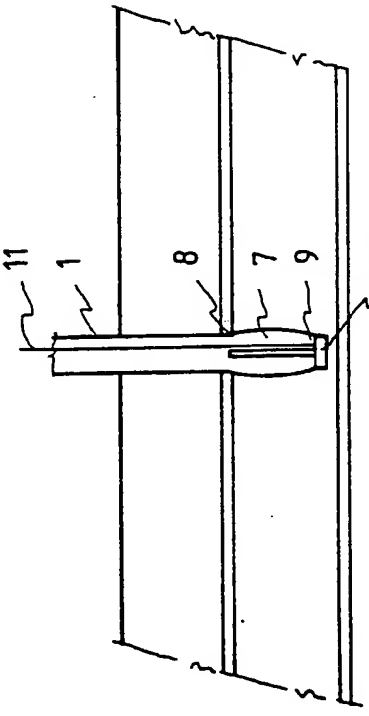

Fig 7

Fig 9b

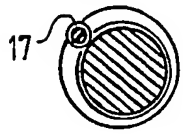

Fig 9a

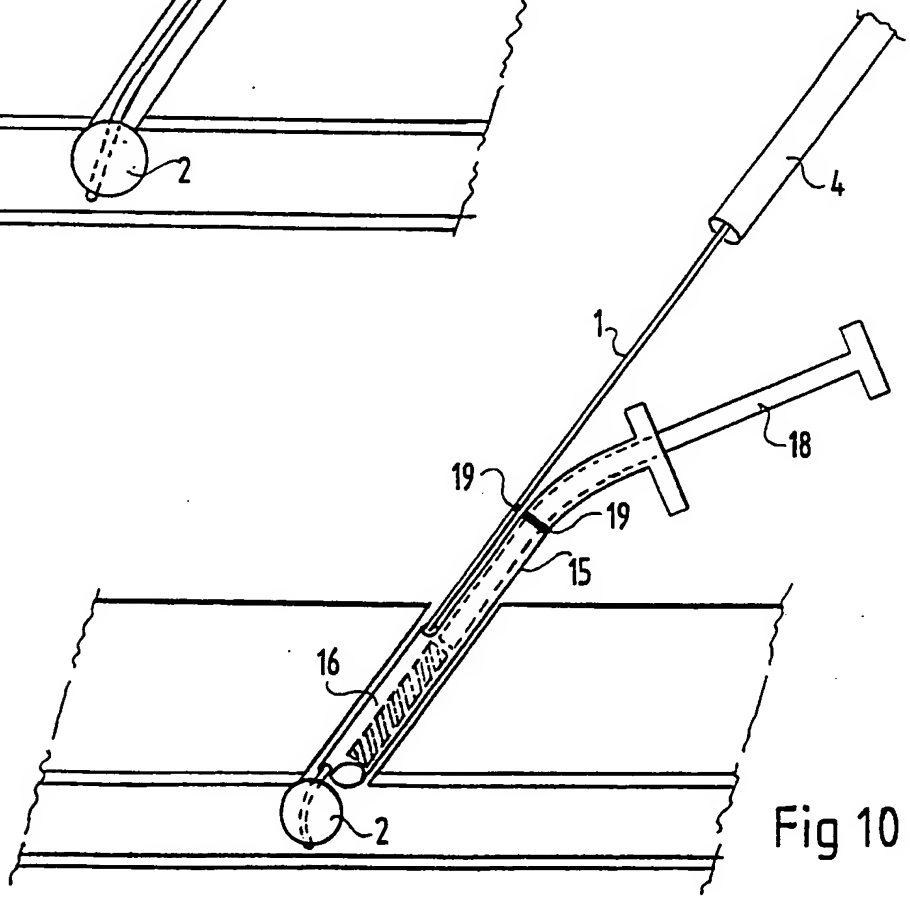

Fig 10

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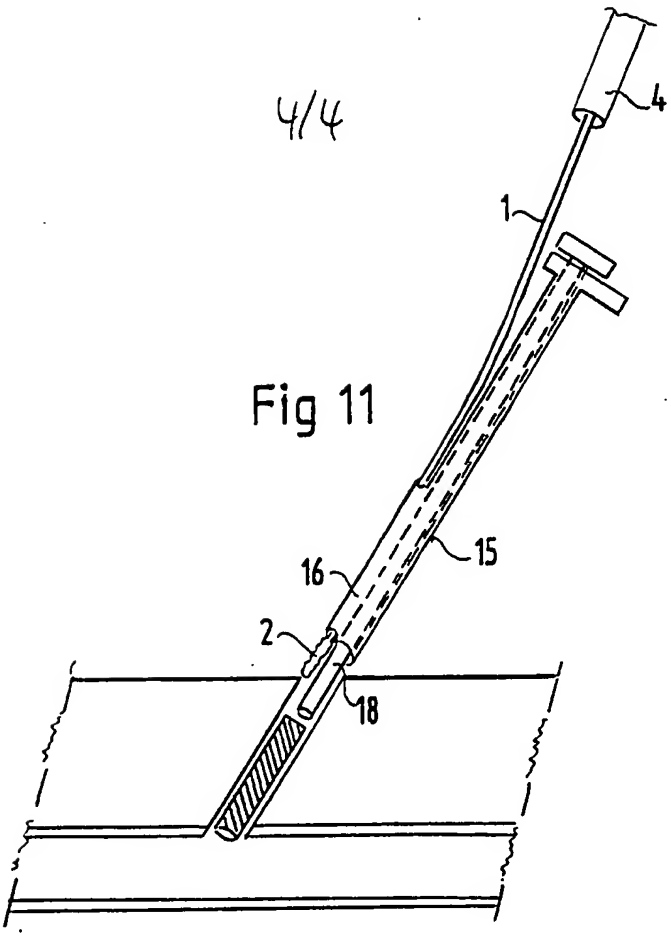

Fig 11

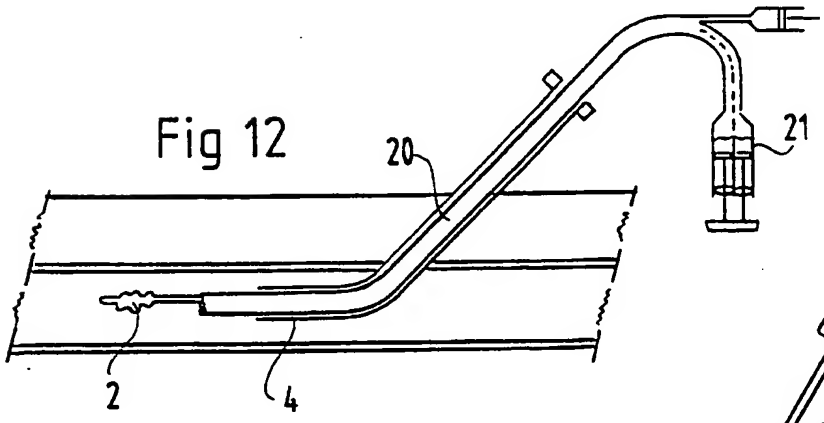

Fig 12

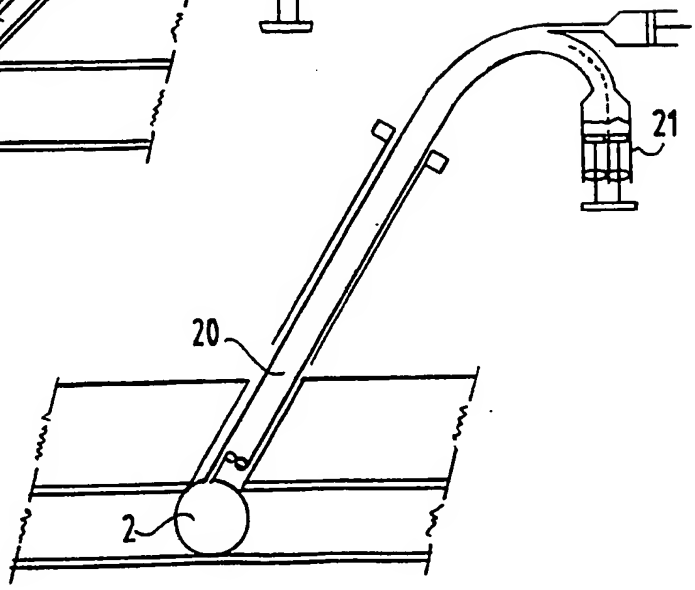

Fig 13

INTERNATIONAL SEARCH REPORT

International Application No. PCT/EP 92/01418

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all)[6]

According to International Patent Classification (IPC) or to both National Classification and IPC

Int.Cl. 5 A61B17/00; A61B17/12

II. FIELDS SEARCHED

Minimum Documentation Searched[7]

Classification System	Classification Symbols
Int.Cl. 5	A61B ; A61M ; A61F

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched[8]

III. DOCUMENTS CONSIDERED TO BE RELEVANT[9]

Category °	Citation of Document, [11] with indication, where appropriate, of the relevant passages [12]	Relevant to Claim No.[13]
A	WO,A,8 911 301 (KENSEY) 30 November 1989 see page 10, line 8 - page 12, line 5; figures 6-8	1
A	WO,A,9 100 752 (ZIMMON) 24 January 1991 see page 9, line 24 - page 10, line 9; figure 1	1,2
A	US,A,4 608 965 (ANSPACH, JR ET AL.) 2 September 1986 see column 1, line 65 - column 2, line 5; figures 1,2	1,4

° Special categories of cited documents :[10]

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IV. CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
30 OCTOBER 1992	09. 11. 92

International Searching Authority	Signature of Authorized Officer
EUROPEAN PATENT OFFICE	MOERS R.

ANNEX TO THE INTERNATIONAL SEARCH REPORT ON INTERNATIONAL PATENT APPLICATION NO. EP 9201418 SA 63529

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report.
The members are as contained in the European Patent Office EDP file on
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Patent document cited in search report	Publication date	Patent family member(s)		Publication date
WO-A-8911301	30-11-89	US-A-	4890612	02-01-90
		EP-A-	0422046	17-04-91
		JP-T-	3505048	07-11-91
WO-A-9100752	24-01-91	AU-A-	6054490	06-02-91
US-A-4608965	02-09-86	None		

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For more details about this annex : see Official Journal of the European Patent Office, No. 12/82